

CLAIMS

What is Claimed is:

1. A method of treatment, comprising:

a) providing:

i) a subject with symptoms of inflammatory bowel disease, and

ii) a therapeutic composition comprising a biologically active vitamin D compound; and

b) administering said therapeutic composition to said subject under conditions such that said symptoms are reduced.

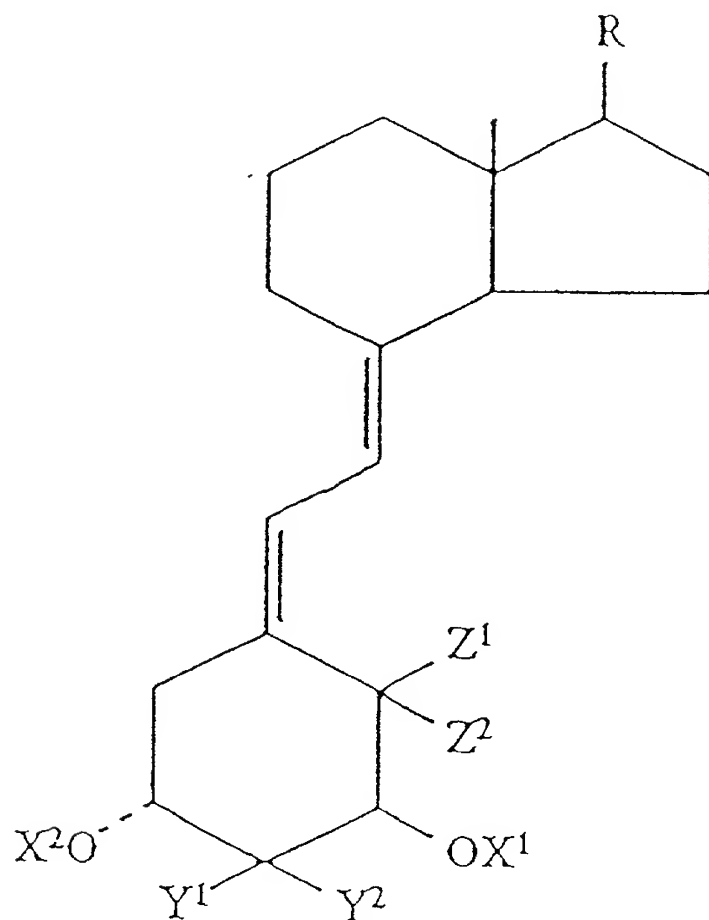
2. The method of Claim 1, wherein said subject is a mammal.

3. The method of Claim 1, wherein the subject is selected from a human, non-human primate, horse, dog, and cat.

4. The method of Claim 1, wherein said therapeutic composition further comprises a transdermal patch.

5. The method of Claim 1, wherein said biologically active vitamin D compound is selected from the group of vitamin D, $1\alpha,25-(\text{OH})_2-16\text{-ene-D}_3$, $1\alpha,25-(\text{OH})_2-24\text{-oxo-}16\text{-ene-D}_3$, $1\alpha,24\text{R}(\text{OH})_2\text{-D}_3$, $1\alpha,25(\text{OH})_2\text{-}22\text{-oxa-D}_3$, $20\text{-epi-}22\text{-oxa-}24\text{a},24\text{b,-dihomo-}1\alpha,25(\text{OH})_2\text{-D}_3$, $20\text{-epi-}22\text{-oxa-}24\text{a},26\text{a},27\text{a,-trihomo-}1\alpha,25(\text{OH})_2\text{-D}_3$, $20\text{-epi-}22\text{-oxa-}24\text{homo-}1\alpha,25(\text{OH})_2\text{-D}_3$, $1,25-(\text{OH})_2\text{-}16,23\text{E-diene-}26\text{-trifluoro-}19\text{-nor-D}_3$.

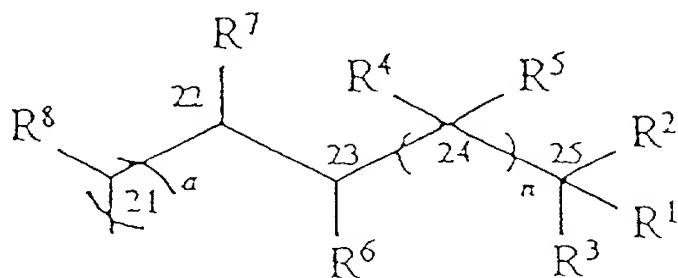
6. The method of Claim 1, wherein said biologically active vitamin D compound is selected from the analogs represented by the following formula:



wherein X^1 and X^2 are each selected from the group consisting of hydrogen and acyl;

wherein Y^1 and Y^2 can be H, or one can be O-aryl or O-alkyl while the other is hydrogen and can have a β or α configuration; Z^1 and Z^2 are both H or, Z^1 and Z^2 taken together are CH_2 ; and

wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R may represent the following side chain:



wherein (a) may have an S or R configuration and wherein R¹ represents hydrogen, hydroxy or O-acyl, R² and R³ are each selected from the group consisting of alkyl, hydroxyalkyl and fluoroalkyl, or, when taken together represent the group--(CH₂)_m--where m is an integer having a value of from 2 to 5, R⁴ is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoroalkyl, R⁵ is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or, R⁴ and R⁵ taken together represent double-bonded oxygen, R⁶ and R⁷ taken together form a carbon--carbon double bond and R⁸ may be H or CH₃, and wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

7. The method of Claim 1, wherein said administration is 0.1-20 µg per day per 160 pound subject.

8. The method of Claim 1, wherein said administration does not cause serious hypercalcemia.

9. The method of Claim 1, wherein said administration does not cause symptoms of hypercalcemia.

10. The method of Claim 1, wherein the route of administration is selected from intravenously, orally, parenterally, topically, and rectally.

11. The method of Claim 1, wherein said biologically active vitamin D compound is administered in a therapeutically effective amount.

12. The method of Claim 11, wherein said therapeutically effective amount is the maximum the patient can tolerate without developing serious hypercalcemia.

13. A method of treatment, comprising:

a) providing:

i) a subject at risk for inflammatory bowel disease, and

ii) a therapeutic composition comprising a biologically active

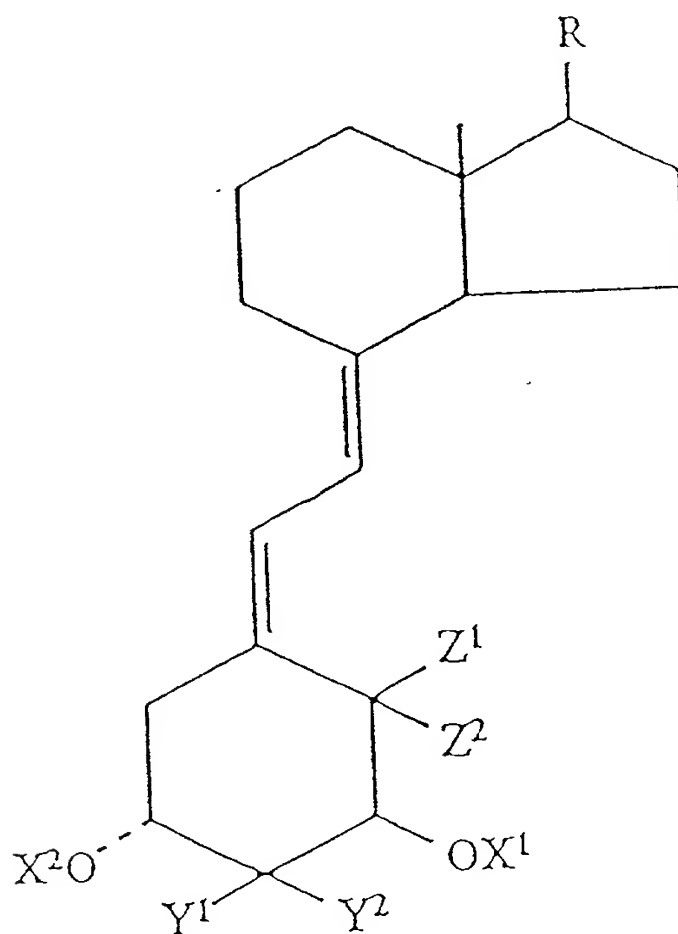
vitamin D compound; and

b) prophylactically administering said therapeutic composition to said

subject.

14. The method of Claim 13, wherein said biologically active vitamin D compound is selected from the group of vitamin D, $1\alpha,25-(\text{OH})_2-16\text{-ene-D}_3$, $1\alpha,25-(\text{OH})_2-24\text{-oxo-16-ene-D}_3$, $1\alpha,24\text{R}(\text{OH})_2\text{-D}_3$, $1\alpha,25(\text{OH})_2\text{-22-oxa-D}_3$, 20-epi-22-oxa-24a,24b,-dihomo- $1\alpha,25(\text{OH})_2\text{-D}_3$, 20-epi-22-oxa-24a,26a,27a,-trihomo- $1\alpha,25(\text{OH})_2\text{-D}_3$, 20-epi-22-oxa-24homo- $1\alpha,25(\text{OH})_2\text{-D}_3$, $1,25-(\text{OH})_2\text{-16,23E-diene-26-trifluoro-19-nor-D}_3$.

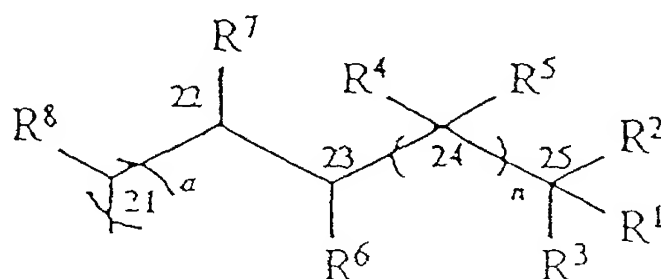
15. The method of Claim 13, wherein said biologically active vitamin D compound is selected from the analogs represented by the following formula:



wherein X^1 and X^2 are each selected from the group consisting of hydrogen and acyl;

wherein Y^1 and Y^2 can be H, or one can be O-aryl or O-alkyl while the other is hydrogen and can have a β or α configuration; Z^1 and Z^2 are both H, or Z^1 and Z^2 taken together are CH_2 ; and

wherein R is an alkyl, hydroxyalkyl or fluoroalkyl group, or R may represent the following side chain:



wherein (a) may have an S or R configuration and wherein R^1 represents hydrogen, hydroxy or O-acyl, R^2 and R^3 are each selected from the group consisting of alkyl, hydroxyalkyl and fluoroalkyl, or, when taken together represent the group-- $(CH_2)_m$ --where m is an integer having a value of from 2 to 5, R^4 is selected from the group consisting of hydrogen, hydroxy, fluorine, O-acyl, alkyl, hydroxyalkyl and fluoroalkyl, R^5 is selected from the group consisting of hydrogen, hydroxy, fluorine, alkyl, hydroxyalkyl and fluoroalkyl, or, R^4 and R^5 taken together represent double-bonded oxygen, R^6 and R^7 taken together form a carbon--carbon double bond and R^8 may be H or CH_3 , and wherein n is an integer having a value of from 1 to 5, and wherein the carbon at any one of positions 20, 22, or 23 in the side chain may be replaced by an O, S, or N atom.

16. The method of Claim 13, wherein said administration delays the onset of symptoms of inflammatory bowel disease.

17. The method of Claim 13, wherein said subject at risk for inflammatory bowel disease is a human.

18. The method of Claim 17, wherein said human is selected from a young adult, a person living in the United States, a person living in England, a person living in Northern Europe, a person of Jewish descent, a person living in a developing nation, a person with family members who suffer from inflammatory bowel disease or a person determined to carry an IBD risk gene.

19. The method of Claim 13, wherein the route of administration is selected from intravenously, orally, parenterally, topically, and rectally.

20. The method of Claim 13, wherein said therapeutic composition further comprises a transdermal patch.